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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,729	01/16/2004	Randall B. Lauffer	13498-019003	6363

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/758,729

Applicant(s)

LAUFFER ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/23/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Arguments***

The amendment filed 5/30/2005 has been entered. Claims 1-66 have been canceled and new claims 67-96 have been added.

***Response to Arguments***

Applicant's arguments with respect to claims 67-96 have been considered but are moot in view of the following new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly presented claims include various limitations that are not described in the specification. For example,

In claim 67:

1) the limitation that R "having from 1 to 5 carbons" is not described in the specification. Nowhere is this specific range of aliphatic compounds set forth in the specification. A

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broad range does not show support for a specific range that may be encompassed thereby.

In claims 67 and 81:

1) the limitation that the MS moiety "comprises an amide bond" was not described in a reasonably generic manner to include this large genus encompassed thereby. The use of "comprising" is open-ended and when defining a chemical moiety would include any moieties having such a bond. There are an unlimited number of chemical moieties having an amide bond. The specification only describes situations wherein the MS is an amide bond or is a carbon nitrogen amide bond linking the amino acids glycine and isoleucine (see page 37). Nowhere does the specification show that applicant envisioned any moiety comprising an amide bond as the MS moiety.

2) the limitation that the MM moiety is a peptide comprising two or positively charged amino acids is not described. The specification fails to describe this subgeneric concept for the MM. While a few specific MMs are described (i.e., tmLys,-tmLys and Ile-Arg-Lys), which have two or more positively charged amino acids, this recitation or the broad recitation that the MM is a peptide, does not show that applicant envisioned the subgenus of any peptide comprising at least two positively charged amino acids.

In claims 68 and 82:

1) the limitation that the MM moiety is a peptide comprising two or more Arg, Lys, or tmLys amino acids is not described in the specification. The specification fails to describe this subgeneric concept for the MM. While a few specific MMs are described (i.e., tmLys,-tmLys and Ile-Arg-Lys, which have two of these amino acids, this recitation or

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the broad recitation that the MM is a peptide, does not show that applicant envisioned the subgenus of any peptide comprising at least two of these amino acids.

In claims 69, 79, 83 and 93:

1) the limitation that MS comprises a Gly amino acid was not described to show support for this subgeneric concept. While the moiety is defined as being a carbon-nitrogen amide bond linking the amino acids glycine and isoleucine, this definition does not show support for the much broader limitation now claimed. Further, nowhere in is the MS defined as being a Gly amino acid as in claim 79.

In claims 70 and 84:

1) the limitation wherein said MS moiety comprises an Arg-Glu dipeptide also was not described. The only recitation concerning this dipeptide and the MS is wherein the MS is the carbon-nitrogen bond of this specific dipeptide, not any peptide the may include such a dipeptide. Note, comprising renders the claim open-ended and would include any moiety that may be substituted with such a dipeptide, which would include proteins, etc.

The limitations in the claims that are discussed above are not properly described because there is nothing in the specification to show these subgeneric concepts were envisioned but the few specific MS moieties and MM moieties described or the very broad definitions thereof described.

The dependent claims fall therewith.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 67 and 81, the recitation of wherein at least one aryl ring of each member of the group is substituted with said –MS-MM moiety is confusing because this recitation does not correspond to the formula which is being defined in the claims, which shows a single attachment of the –MS-MM moiety to the IEM-PBM moiety and therefore does not allow for more than one –MS-MM moiety. This can be corrected by inserting brackets to show that one or more –MS-MM moiety can be present as set forth in the specification, e.g., IEIM-PBM-[MS-MM]<sub>p</sub>.

Claim 81 is confusing in that it defines the composition in a contradictory manner. First it defines the composition as having the formula IEM-PBM-MS-MM in lines 1-2, then it defines the composition as having a structure that appears only to correspond to the IEM-X-PBM, which is confusing. Also, it is unclear where the X of the structure fits into the formula in lines 1-2.

Claim 96 is indefinite because it is not complete itself, but refers to the specification for completeness. Where possible claims are to complete themselves. Ex parte Fressola, 27 USPQ2d 1608, 1609, Bd. Pat. Appls. & Int., 1993.

The dependent claims fall therewith.

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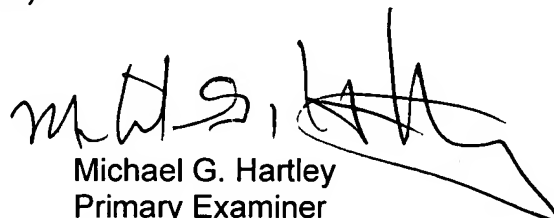
**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1618

7/25/2005